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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/676,261

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EXAMINER

KIM, TAEYOON

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

07/25/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/676,261

Applicant(s)

HUSSAIN, MEHBOOB

Examiner

Taeyoon Kim

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5 and 7-22 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 7-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4 and 16-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1, 3-5 and 7-22 are pending.

Response to Amendment/Argument

Applicant's amendment and response filed on Dec. 21, 2006 has been received and entered into the case.

Claims 2 and 6 are canceled, claims 16-22 are newly added, and claims 5 and 7-15 are withdrawn from consideration as being drawn to non-elected subject matter. Claims 1, 3, 4 and 16-22 have been considered on the merits. All arguments have been fully considered.

The claim rejection under 35 U.S.C. § 112 made to claims 1-4 is withdrawn due to the amendment.

Claim Objections

Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The limitation disclosed in claim 3 is already present in claim 1. Therefore, claim 3 no longer further limits the parent claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 4 and 16-22 are rejected under 35 U.S.C. 112, second paragraph,

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as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 discloses the phrase "depleted of hematopoietic cells..." It is not clear whether "hematopoietic cells" includes "hematopoietic stem cells." Since hematopoietic stem cells are also considered as hematopoietic cells, it is not clear whether the subpopulation of bone marrow disclosed in claim 1 is depleted of hematopoietic stem cells.

Claim 1 discloses the term "human adult bone marrow cells." It is not clear whether the bone marrow is from "adult" human or the term "adult" means as in "embryonic" vs. "adult" stem cells, meaning non-embryonic cells. Clarification is required.

The term "the cells" in line 3 of claim 1 does not clearly point out what subject matter it intends to claim. There are "human adult bone marrow cells", "hematopoietic cells", "leukocytes" and "the subpopulation of human adult bone marrow cells" listed in the claim. Although it appears that the term intends to point out "the subpopulation of human adult bone marrow cells", it is vague which cells the claim points out. Clarification is required.

Claim 1 recites the limitation "the pancreas" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102/§103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 4 and 16-22 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pittenger et al. (1999, Science) or Fernandez et al. (US 6,261,549; IDS reference) in light of Levanduski (US 2003/0113910) and Holden et al. (2002, Science; IDS reference).

Claims 1, 3, 4 and 16-22 are drawn to an isolated subpopulation of human bone marrow cells, which are depleted differentiated hematopoietic cells including leukocytes having at least 20% of the cells in the subpopulation with a phenotype of CD45-, Lin- and Sca+, and having an ability to home to pancreas and differentiating into insulin-producing pancreatic islet cells, and a composition comprising the isolated subpopulation of claim 1 and a pharmaceutically-acceptable carrier, and the limitations to the subpopulation wherein at least 30, 40, 50, 60, 70, 80 or 90% of the subpopulation cells having the phenotype.

Pittenger et al. disclose and Fernandez et al. both disclose human mesenchymal stem cells (HMSCs) isolated from bone marrow or peripheral blood (see Abstract). Pittenger et al. and Fernandez et al. disclose the HMSCs lack expression of CD45 (CD45-) (see p.144, first column of Pittenger et al.; column 6, lines 61-63 of Fernandez

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et al.).

Although Pittenger et al. or Fernandez et al. do not exclusively disclose those HMSCs having Lin- and Sca+, this particular phenotype is an inherent property of HMSCs as evidenced by Levanduski (US 2003/0113910). Levanduski teaches that MSCs express Sca-1 (Sca+) and would not express Lin (Lin-) (see Table 3 in p.20).

Thus, the HMSCs of Fernandez et al. would inherently be Lin-, Sca+ and CD45-.

M.P.E.P. §2112 states that "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). >In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel." Therefore, a holding of anticipation is clearly required.

Although Fernandez et al. do not particularly disclose the ability of the HMSCs to home to pancreas to differentiate into insulin-producing pancreatic islet cells, since the

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HMSCs are considered identical as the subpopulation of bone marrow cells of the claimed invention, it would have been also an inherent property of HMSCs of Fernandez et al. to accomplish the same function as the cells claimed in the instant application. Furthermore, it is understood that stem cells from bone marrow would possess a potential to differentiated into various different organs/tissues including pancreas as disclosed by Holden et al. (see Figure in p.2126).

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cell population differs, and if so to what extent, from the HMSCs discussed in Fernandez et al. Accordingly, it has been established that the prior art HMSCs, which (has the same human cells isolated from bone marrow), demonstrates a reasonable probability that it is either identical or sufficiently similar to the claimed cell population that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

Merely because a characteristic of a known cell population is not disclosed in a reference does not make the known cell population patentable. The new cell population possesses inherent characteristics which might not be displayed in the tests used the reference. Clear evidence that the HMSCs of the cited prior art do not possess a critical characteristic that is possessed by the claimed subpopulation of human adult bone marrow cells, would advance prosecution and might permit allowance of claims to applicants' invention.

Therefore, the reference of Fernandez et al. in light of Levanduski anticipates the

claimed invention, or renders the claimed invention obvious.

Conclusion

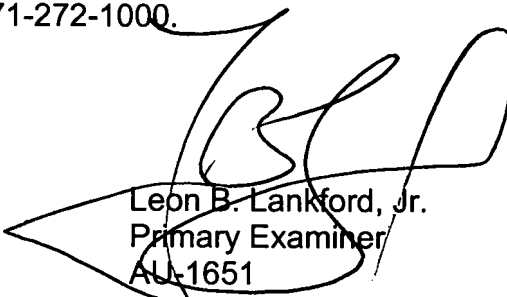
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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